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July 28, 1997

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street S.W. Washington, D.C. 20204

0260 '97 SEP 19 P1 :55

AUG - 5

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, LEINER HEALTH PRODUCTS notifies the FDA that it has begun using the following phrase and statement:

May Help Reduce Body Fat

CLA (Conjugated Linoleic Acid) is derived from natural sunflower oil. Animal studies suggest CLA helps in repartitioning, a process that directs calories toward muscle and away from body fat.

A preliminary human trial also showed improved muscle - body fat ratio without weight loss.

on the following product:

Your Life® Tonalin

Very truly yours,

LEINER HEALTH PRODUCTS

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs William Cochran, Regulatory Affairs Associate

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